



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,752	10/19/2001	Reinhold Schmieding	P/1493-443	6145
24998	7590	08/09/2006	EXAMINER	
DICKSTEIN SHAPIRO LLP			NAJARIAN, LENA	
1825 EYE STREET NW			ART UNIT	PAPER NUMBER
Washington, DC 20006-5403			3626	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/981,752	SCHMIEDING, REINHOLD	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lena Najarian	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 June 2006.
- 2a) This action is **FINAL**.                                   2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-17 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Notice to Applicant***

1. This communication is in response to the amendment filed 6/21/06. Claims 1-17 remain pending. Claims 1, 2, 8, and 14 have been amended.

***Claim Rejections - 35 USC § 112***

2. The rejection of claims 1-17 under 35 U.S.C. 112 are hereby withdrawn due to the amendment filed 6/21/06.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) The amendment to claim 1 was apparently made to overcome 112, 2<sup>nd</sup> paragraph issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous

Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

(B) Claim 7 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

5. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning") in view of Tubo et al. (5,040,677), and further in view of Hamada (US 6,425,920 B1).

(A) The amendment to claim 2 was apparently made to overcome 112, 2<sup>nd</sup> paragraph issues set forth in the prior Office Action. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

(B) Claim 3 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

6. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning"), and further in view of Ramshaw et al. (5,791,907).

(A) Claims 4-6 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

7. Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US 6,425,920 B1) in view of Tubo et al. (5,040,677), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning").

(A) The amendment to claim 8 was apparently made to overcome 112, 2<sup>nd</sup> paragraph issues set forth in the prior Office Action and for purposes of clarity. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

(B) Claim 13 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

8. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US 6,425,920 B1) in view of Tubo et al. (5,040,677), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning") and Alten (4,852,554).

(A) Claim 9 has not been amended and is rejected for the same reasons given in the previous Office Action, and incorporated herein.

9. Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamada (US 6,425,920 B1) in view of Tubo et al. (5,040,677), and further in view of AORN Journal ("Flash pans; survey process; sterilizing endoscopes; equipment rental; surgical zippers; abbreviations; floor cleaning") and Ramshaw et al. (5,791,907).

(A) Claims 10-12 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

10. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alten (4,852,554) in view of Tubo et al. (5,040,677), and further in view of Ramshaw et al. (5,791,907).

(A) The amendment to claim 14 was apparently made to overcome 112, 2<sup>nd</sup> paragraph issues set forth in the prior Office Action and for purposes of clarity. However, these changes do not affect the scope and breadth of the claim as originally presented and/or in the manner in which the claim was interpreted by the Examiner when applying prior art within the previous Office Action. As such, this claim is rejected under the same rationale given in the prior Office Action, and incorporated herein.

(B) Claims 15-17 have not been amended and are rejected for the same reasons given in the previous Office Action, and incorporated herein.

***Response to Arguments***

11. Applicant's arguments filed 6/21/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 6/21/06.

- (1) Applicant argues at pages 7 and 12 that Alten is silent about allografts or about customizing an allograft to be used in a predetermined surgical procedure.
- (2) Applicant argues at page 7 that AORN does not rectify the deficiencies of Alten.
- (3) Applicant argues at page 11 that Hamada teaches spinal fusion implants, and not the steps recited in claim 8. Tubo and AORN also fail to disclose, teach or suggest any of the limitations of claim 8.

(A) As per the first argument, the Examiner respectfully submits that Alten discloses bones that have been harvested for bone banks and bone transplant surgery (see abstract and col. 1, lines 12-16 of Alten). As such, it is readily apparent that Alten is not silent about allografts and that the bone is to be prepared for use in a predetermined surgical procedure.

(B) In response to applicant's argument that AORN does not rectify the deficiencies of Alten, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have

suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(C) As per the third argument, the Examiner is concerned that, aside from merely alleging that certain claimed features are not obvious from Hamada, Tubo, and AORN, essentially in the form of blanket statements, Applicant does not point to any specific distinction(s) between the features disclosed in the references and the features that are presently claimed. In particular, 37 CFR 1.111(b) states, "A general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the reference does not comply with the requirements of this section." Applicant has failed to specifically point out HOW the language of the claims patentably distinguishes them from the applied references. Also, arguments or conclusions of Attorney cannot take the place of evidence. *In re Cole*, 51 CCPA 919, 326 F.2d 769, 140 USPQ 230 (1964); *In re Schulze*, 52 CCPA 1422, 346 F.2d 600, 145 USPQ 716 (1965); *Mertizner v. Mindick*, 549 F.2d 775, 193 USPQ 17 (CCPA 1977).

### ***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lena Najarian whose telephone number is 571-272-7072. The examiner can normally be reached on Monday - Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Ln*  
In

*Joseph Thomas*  
JOSEPH THOMAS  
SUPERVISORY PATENT EXAMINER

Application/Control Number: 09/981,752  
Art Unit: 3626

Page 9

7-24-06